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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,332	12/15/2003	Rong Jian Yang	USP2342H-JMG	7563

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/737,332	YANG ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-20* is/are rejected.

7)☒ Claim(s) *9-17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/31/06 has been entered.

2. Applicant's amendment filed 8/31/06 has been entered.
Upon further consideration, the restriction requirement set forth 6/28/05 has been withdrawn.

Claims 1 and 4 - 20 are under consideration in the instant application.

3. Applicants' are invited to submit IDS for consideration.

4. Claims 9-17 are objected to as being depended on cancelled claims.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1 and 4-20 contain the trademark/trade name, SEPHADEX A50 and SEPHADEX G200. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe diethylaminoethyl cellulose and, accordingly, the identification/description is indefinite.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1 and 4-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 4,725,428 (of record) in view of U.S. Pat. No. 5,972,312 (of record) and Akita et al. (Journal of Food Science, 1992, 57(3):629-634, of record) for the reasons set forth in the office action mailed 3/27/06.

The '428 patent teaches a dental caries preventive composition comprising antibody to *Streptococcus mutans* and sodium benzoate (col. 12-14, Example 4-9, Abstract, claims 1-16, in particular). The '428 patent further teaches that the antibody concentration ranges 0.002 to 5% (col. 4, lines 18-23, in particular), addition of well known ingredients depending on the type and form of a particular composition (col. 6, lines 56-65, in particular) and packaging of proper container for storage and convenient use (col. 7, lines 61-65, in particular).

The '428 patent does not explicitly teach IgY antibodies, combination of preservatives and packaging in atomizer or sucking bottle.

However, the '312 patent teaches the oral composition for tooth decay containing bactericide (i.e. composition against dental caries bacteria (abstract, col. 10, lines 23-35, in particular) and it is well known in dental product industry to add combination of preservatives or stabilizers as long as the effects of composition are not lessened (col. 4, lines 13-18, in particular).

The '312 patent further teaches the combination of sodium benzoate and potassium sorbate as preservatives (col. 5, lines 13-16, in particular) in the amount of from 0.01 to 1.0%. The '312 patent also teaches packaging oral compositions in pump dispenser (i.e. spray type, col. 5, lines 40-55, in particular) and container of the squeeze type (i.e. sucking bottle, col. 5, lines 40-55, in particular) for convenience to use and ease to regulate dose.

However, Akita et al. teach advantages of using IgY antibodies. The IgY offers conventional antibody production, producing more specific antibodies against mammalian antigen and low cost to produce (p. 629, introduction, in particular).

Applicants' arguments filed 8/31/06 have been fully considered but they are not persuasive.

Applicants traversed the rejection based on that the antibody used in the '428 patent is a mixture (polyclonal or mixture of different classes) and the one of the ordinary skill in the art would not know which components exert inhibitory effect. Applicant further argues that the '428 patent does not teach IgY.

Claims 6-20 are included in this rejection because a product is a product irrespective of how it is made. Claims 6-20 do not result a structurally different product from claim 1. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir, 1985). See MPEP 2113

Contrary to Applicants' argument, the '428 patent particularly teaches the serotype c is preferably used (claim 2, col. 2, lines 45-50, in particular). In addition, classification of antibodies is irrelevant to the claimed invention as the claimed invention is drawn to IgY. Furthermore, the '428 patent teaches S. mutans causes dental caries (col. 1, lines 20-36), serotypes c, d, e, f and g may be preferably used (col. 2, lines 45-50). It is prima facie obvious to combine two compositions (serotype c or serotype d) each of which is taught by prior art to be useful for same purpose in order to form third composition (serotypes c and d) that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. In re Kerkhoven, 205 USPQ 1069, CCPA 1980. See MPEP 2144.06.

The use of stabilizer (e.g. humectants, sorbitol, sorbitan, '312 patent, col.4, lines 6-35) in dental product industry is well known. As discussed in the office action mailed 3/27/06, it is well known in dental product industry to add combination of preservatives or stabilizers as long as the effects of composition are not lessened ('312 patent, col. 4, lines 13-18). Having "antiseptic" being any substance prevents growth of the microorganisms, the addition of sodium benzoate and/or potassium sorbate achieves the intended purpose as well as preservatives or stabilizers.

In addition, given the claimed invention is drawn to a dental combination, a composition is a composition irrespective of how it is made, the patentability of the product is not depended on its method.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add sodium benzoate and/or potassium sorbate as taught by the '312 patent and raise the S. mutans antibody in hens (IgY) as taught by Akita et al. with the oral formulation taught by the '428 patent.

One of the ordinary skill in the art would have been motivated to do so because the addition of sodium benzoate and/or potassium sorbate adds stability and raising IgY antibody reduces cost of production.

From the teachings of references, it would have been obvious to one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

It is the Examiner's position the combination of reference teachings remains obvious.

9. Claims 1 and 4-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/04804 as is evidenced by Ooshima et al. (J. Dental Res 60(4):855-859, 1981) in view of U.S. Pat. No. 5,972,312 (of record).

The '804 publication teaches that the use of IgY antibody against S. mutans which causes dental caries (claims 3-7, 13, 14, 20-24, p. 8-10, 11, 14 in particular) to prevent dental caries. The '804 publication teaches that the concentration of IgY is 0.15% and produced by the immunizing, extracting crude and

separating by ion-exchange and gel chromatography such as DEAE and Sephadex Gel (Examples 6-7, 12, in particular).

As is evidenced by Ooshima, among S. mutans serotypes, serotypes c and d induce dental caries (abstract, conclusion, in particular). Thus, the dental caries causing S. mutans are serotypes c and d.

The '804 publication does not teach use of potassium sorbate and/or sodium benzoate and packaging in a sucking bottle.

Claims 6-20 are included in this rejection because the patentability of the product does not depend on its method of production. Claims 6-20 do not result a structurally different product from claim 1. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir, 1985). See MPEP 2113.

However, the '312 patent teaches the oral composition for tooth decay containing bactericide (i.e. composition against dental caries bacteria (abstract, col. 10, lines 23-35, in particular) and it is well known in dental product industry to add combination of preservatives or stabilizers as long as the effects of composition are not lessened (col. 4, lines 13-18, in particular).

The '312 patent further teaches the combination of sodium benzoate and potassium sorbate as preservatives (col. 5, lines 13-16, in particular) in the amount of from 0.01 to 1.0%. The '312 patent also teaches packaging oral compositions in pump dispenser (i.e. spray type, col. 5, lines 40-55, in particular) and container of the squeeze type (i.e. sucking bottle, col. 5, lines 40-55, in particular) for convenience to use and ease to regulate dose.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add sodium benzoate and/or potassium sorbate and packaging it in a sucking bottle as taught by the '312 patent to the IgY dental caries preventive formulation taught by the '804 publication.

One of the ordinary skill in the art would have been motivated to do so because the addition of sodium benzoate and/or potassium sorbate adds stability to the IgY dental formulation and packaging it in a sucking bottle adds convenience as well as dispensing to regulate dose.

From the teachings of references, it would have been obvious to one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1 and 4-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-16 of copending Application No. 10/547,237 in view of U.S. Pat. No. 5,972,312. This is a provisional obviousness-type double patenting rejection.

The '237 application teaches a toothpaste (e.g. combination) of against dental caries bacteria using IgY against S. mutans, serotypes c and d.

The '237 application does not teach use of potassium sorbate and/or sodium benzoate and packaging in a sucking bottle.

However, the '312 patent teaches the oral composition for tooth decay containing bactericide (i.e. composition against dental caries bacteria (abstract, col. 10, lines 23-35, in particular) and it is well known in dental product industry to add combination of preservatives or stabilizers as long as the effects of composition are not lessened (col. 4, lines 13-18, in particular).

The '312 patent further teaches the combination of sodium benzoate and potassium sorbate as preservatives (col. 5, lines 13-16, in particular) in the amount of from 0.01 to 1.0%. The '312 patent also teaches packaging oral compositions in pump dispenser (i.e. spray type, col. 5, lines 40-55, in particular) and container of the squeeze type (i.e. sucking bottle, col. 5, lines 40-55, in particular) for convenience to use and ease to regulate dose.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add sodium benzoate and/or potassium sorbate and packaging it in a sucking bottle as taught by the '312 patent to the IgY dental caries preventive formulation taught by the '237 application.

One of the ordinary skill in the art would have been motivated to do so because the addition of sodium benzoate and/or potassium sorbate adds stability to the IgY dental formulation and packaging it in a sucking bottle adds convenience as well as dispensing to regulate dose.

From the teachings of references, it would have been obvious to one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. No claims are allowable.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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November 2, 2006

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